FEB 1 1 2000

K000144

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted as required by SMDA of 1990.

Date:	November 14, 1999
Applicant:	NIPRO Medical Corporation
Address:	3150 NW 107th Ave Miami, FL 33172
Establishment Reg. #:	1056186
Contact Person:	Cary Goldsmith
Title:	Product Manager
Telephone:	(888) 647-7698
Telefax:	(305) 599-8454

a. Trade Name: NIPRO Insulin Syringe

b. Common Name: Insulin Syringe

c. Classification of Device: Piston Syringe
HO FMF
Class II (performance standards)
21 CFR 880.5860

d. Identification of Predicate Device(s):

	510(k) #
Aimsco Delta Hi-Tech Insulin Syringe	K882114
Becton Dickinson Syringe	K980580

e. Intended use:

The NIPRO Insulin Syringe is intended for use for the subcutaneous injection of insulin. Its function is mechanical.

f. Device Description:

The NIPRO Insulin Syringe is a sterile, single-use insulin syringe designed for manual use. The syringe is provided in two sizes, ½ cc and 1 cc. The syringe consists of a barrel, a plunger rod with synthetic rubber gasket, a fixed 28 gauge needle and two end-caps over the needle and plunger to preserve sterility of the fluid path. The syringes are intended for mechanical injection of U-100 insulin.

g. Technological Characteristics and Rationale for Substantial Equivalence:

The NIPRO Insulin Syringe is substantially equivalent to the predicate Aimsco Syringe in the following characteristics:

- Design
- Physical characteristics
- Material composition
- Intended use

The packaging configuration of the NIPRO Insulin Syringe and the Becton Dickinson Syringe is similar.

h. Safety and Performance Studies:

There are no significant differences to the insulin syringe from the predicate device(s) which could affect safety, effectiveness or intended use. Testing summary:

- Pyrogenicity
- Systemic Toxicity
- pH Difference
- Sterility
- Heavy Metals
- Foreign Materials in the Barrel
- Dead Space
- Gasket Inertness
- Barrel Markings
- Syringe Accuracy
- Air Leakage
- KMnO4 Reduction
- Evaporation Residue
- Intracutaneous Test
- Plunger Movement
- Needle Dimensions
- Needle Corrosion
- Needle Breakage
- Needle Elasticity and Stiffness
- Hub/Needle Strength
- Needle Cannula Brokage

The results of each test were found to be acceptable.

i. Conclusions:

Based upon the indications for use, technological characteristics, and safety and performance studies, the NIPRO Insulin Syringe has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2000

Mr. Cary Goldsmith
Product Manager
Nipro Medical Corporation
3150 N.W. 107 Avenue
Miami, Florida 33172

Re: K000144
Trade Name: Nipro Insulin Syringe
Regulatory Class: II
Product Code: FMF
Dated: January 6, 2000
Received: January 18, 2000

Dear Mr. Goldsmith:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Susan Runner

for Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: NIPRO Insulin Syringe

Indications for Use:

The NIPRO Insulin Syringe is intended for the subcutaneous injection of insulin. Its function is mechanical.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

Patricia Cicenia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K000144